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EXAMINER	
KRAMER, NICOLE R	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/030,973	HOFFER, JOAQUIN ANDRES
	Examiner	Art Unit
	Nicole R. Kramer	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 18 September 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 20-31,33,34,36-42,44-49,51,52,54-63,65,66,68-70,73,74 and 76-85 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20-31,33,34,36-42,44-49,51,52,54-63,65,66,68-70,73,74 and 76-85 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 20-21, 23-31, 33-34, 36-38, 41-42, 44-49, 51-52, 54-56, 59-61, 63, 65-66, 68-69, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso) in view of "Discrimination of Phantom Hand Sensations Elicited by Afferent Electrical Nerve Stimulation in Below-Elbow Amputees" (Anani et al.).

In the previous Office Action dated 7/21/2005, Examiner provided applicant a copy of Riso from Technology and Health Care (Fall 1999). Examiner also provided applicant with citation that the same paper was previously published in "Proceedings of the International Biomechatronics Workshop" on April 1999, and therefore constitutes prior art under 35 U.S.C. 102(a).

Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4). The system comprises a plurality of sensors in the prosthetic limb, a microprocessor/controller for signal encoding in the prosthetic limb, a multichannel stimulator for receiving information

from the microprocessor/controller and producing electrical stimulation signals to stimulate one or more sensory nerve fibers of a severed limb nerve, and a neuro-interface for transmitting electrical stimulation signals to selected sensor nerve fibers (see description of Fig. 4 on pages 406-407). Riso discloses that stimulation of one or more selected sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors (see page 403; section entitled “Microstimulation of tactile afferents”). In addition, Examiner considers the electrical signals to approximate a pattern of sensations that would be received from a normal, innervated limb before it was amputated because the microelectrical stimulation of small bundles of afferents described in Riso approximates natural sensations more than macrostimulation, which results in a low quality of perceived sensation that remains a foreign feeling resembling a vibration, taping, or flutter on the skin (see page 402 of Riso describing undesirability of macrostimulation). Riso discloses that the microelectrical stimulation should facilitate the independent activation of tactile and muscle afferents (see page 407).

Riso discloses that as a result of developments in FES and cochlear neuroprostheses, a number of commercial stimulators are available for use and *the parameters for safe nerve stimulation are becoming clearly defined* (emphasis added) (see page 407). However, Riso fails to explicitly disclose the stimulation parameters used to approximate natural sensations - in particular, Riso fails to disclose that the electrical stimulation signals include impulses having a duration in the range of about 10 to 1000 microseconds and a current amplitude 1-10 times a current threshold required

to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. Anani et al. describes experimentation with nerve stimulation of an amputation stump, and describes that the stimulus was delivered from a current stimulator providing negative pulses of 0.1 ms width (see first full paragraph on page 132). The intensity range used was between 0.4 mA and 3.0 mA (see first full paragraph on page 132), which is necessarily at a current amplitude 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber because Anani teaches that the subjects felt the stimulation (and thus was necessarily above the current threshold) but that no discomfort or pain was elicited (see Results section on page 132). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Riso to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claims 21, 42, 61, and 70, Riso discloses that single pulses vs. pulse trains elicit differing patient sensations (see page 403; section entitled "Microstimulation of tactile afferents"). Examiner considers such patient feedback regarding the type of electrical stimulation to anticipate the recitation that the selection of the electrical stimulation signals is based on feedback from the patient.

With respect to claims 23-26, 29, 44-46, and 48, Riso discloses an embodiment in which the microprocessor is located inside the prosthetic limb and the multi-channel stimulator is implanted in the patient's stump (see Fig. 4). It would have been obvious

to one having ordinary skill at the time of applicant's invention to rearrange the parts such that both the microstimulator and the multi-channel stimulator are both within the prosthetic or implanted within the stump, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70.

With respect to claims 27 and 63, Riso discloses finger position and grasp force sensors (see Fig. 4).

With respect to claims 28 and 47, Riso discloses that the means for communicating the sensor signals to the stump are telemetric (communicator in prosthesis/implanted receiver in stump).

With respect to claim 30, Riso discloses an implanted receiver in the stump. The recitation that the electrical stimulation signals are supplied "to alleviate phantom limb pain when the prosthetic limb in not in use" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claim 31, 41, 49, and 59, Riso discloses that the means for communicating the sensor signals to the stump are telemetric (communicator in prosthesis/implanted receiver in stump). Non-electrical (i.e., telemetric), electrical, and optical signal transmission are all well known in the art and recognized as equivalents. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to use either form of signal transmission because the selection of

any of the art-recognized equivalents to transmit signals would be within the level of ordinary skill in the art.

With respect to claims 33, 51, 65, 78, 80, and 82, Anani et al. describes that the stimulus was delivered from a current stimulator providing negative, square shaped pulses of 0.1 ms width (see first full paragraph on page 132). As described above, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Riso to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claims 34, 52, 66, 79, 81, and 83, Riso discloses that as a result of developments in FES and cochlear neuroprostheses, a number of commercial stimulators are available for use and the parameters for safe nerve stimulation are becoming clearly defined (see page 407). However, Riso does not explicitly teach that the electrical stimulation signals include negative/positive going biphasic pulses. Various tissue stimulators are known in the art for providing biphasic pulses (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Riso to utilize such tissue stimulators for applying biphasic pulses since bipolar stimulating pulses significantly reduce the voltage pulse decay time, and thus the level on the electrode leads returns to its quiescent state

immediately after each stimulating pulse terminates (see col. 20, lines 33-53 of Schulman).

With respect to claims 36-37, 54-55, and 68-69, adjustment of stimulation parameters is known in the art (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). For example, it is known that individual thresholds differ from one patient to another, and thus adjustment of the current intensity may be necessary to avoid causing pain or discomfort to the patient. In addition, it is known that patient's may adapt to stimulation parameters, and thus require an adjustment in order to elicit the desired sensations.

With respect to claims 38 and 56, Riso discloses several embodiments of microelectrode nerve interfaces (see page 405), including a nerve cuff (embodiments a/b) that circumferentially surrounds a portion of the nerve. Examiner considers a "multi-chambered nerve cuff" to encompass embodiment (a) of Riso in that embodiment (a) includes a guidance chamber that circumferentially surround a portion of the nerve and a plurality of holes (chambers) each of which represent an addressable electrode contact.

3. Claims 22, 62, 70, 73-74, 76-77, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso) in view of "Discrimination of Phantom Hand Sensations Elicited by Afferent Electrical Nerve Stimulation in Below-Elbow Amputees"

(Anani et al.), as applied above, and further in view of U.S. Patent No. 4,232,679 ("Schulman").

As described above, Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4). Riso fails to disclose that electrical stimulation signals should be provided in the absence of sensory signals in order to alleviate phantom limb pain. Schulman teaches that it is known in the art to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40). It would have been obvious to one having ordinary skill in the art to modify the nerve interface of Riso to stimulate an amputee's severed nerve to alleviate phantom limb pain as taught by Schulman because phantom limb pain may occur when the prosthetic limb is not in use (i.e., when the sensors are not controlling the nerve stimulation).

With respect to claims 73 and 84, Anani et al. describes that the stimulus was delivered from a current stimulator providing negative, square shaped pulses of 0.1 ms width (see first full paragraph on page 132). As described above, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Riso to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claims 74 and 85, Riso discloses that as a result of developments in FES and cochlear neuroprostheses, a number of commercial stimulators are

available for use and the parameters for safe nerve stimulation are becoming clearly defined (see page 407). However, Riso does not explicitly teach that the electrical stimulation signals include negative/positive going biphasic pulses. Various tissue stimulators are known in the art for providing biphasic pulses (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Riso to utilize such tissue stimulators for applying biphasic pulses since bipolar stimulating pulses significantly reduce the voltage pulse decay time, and thus the level on the electrode leads returns to its quiescent state immediately after each stimulating pulse terminates (see col. 20, lines 33-53 of Schulman).

With respect to claims 76-77, adjustment of stimulation parameters is known in the art (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). For example, it is known that individual thresholds differ from one patient to another, and thus adjustment of the current intensity may be necessary to avoid causing pain or discomfort to the patient. In addition, it is known that patient's may adapt to stimulation parameters, and thus require an adjustment in order to elicit the desired sensations.

4. Claims 39-40 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso) in view of "Discrimination of Phantom Hand Sensations

Elicited by Afferent Electrical Nerve Stimulation in Below-Elbow Amputees" (Anani et al.), as applied above, and further in view of U.S. Patent No. 5,824,027 ("Chen").

Riso discloses several embodiments of microelectrode nerve interfaces (see page 405), including a nerve cuff (embodiments a/b) that circumferentially surround a portion of the nerve. Riso fails to disclose that electrodes are incorporated within a multi-chambered tubular nerve cuff that includes a number of parallel ridges that provide insulation between electrodes. Chen discloses a multi-chambered tubular nerve cuff that may be used to stimulate a severed nerve. The nerve cuff is multi-chambered (30) with a plurality of sealing ridges (28), and the electrodes (34) are segregated into separate chambers of the nerve cuff. It would have been obvious to one having ordinary skill in the art to modify the nerve interface of Riso to incorporate the electrodes in a multi-chambered tubular nerve cuff as taught by Chen because the nerve cuff of Chen provides a customized fit to the shape and size of a nerve at the time of implantation.

With respect to claims 40 and 58, Chen discloses that tubes 42 may be used to deliver pharmacological agents or other chemicals into a chamber (30) through openings (44) (see col. 8, lines 44-55).

5. Claims 60-61, 63, 63-66, 68-69, and 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,314,495 ("Kovacs") in view of "Discrimination of Phantom Hand Sensations Elicited by Afferent Electrical Nerve Stimulation in Below-Elbow Amputees" (Anani et al.).

Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. The microelectrode interface is used to localize stimulation or detection of action potential to a particular location on the nerve (see col. 6, line 12-14). When the microelectrode interface acts as a stimulator, it is supplied with electrical current from source 32 to provide electrical stimulation to the nerve. Kovacs discloses that a microprocessor (control processor) generates control signals to a stimulus latch 284 to control each pair of microelectrodes for stimulation purposes (see Fig. 9 and associated text). In addition, Kovacs discloses that prosthetic limb 302 may contains sensors for tactile, position, and force sensing which are transmitted by transceiver 306 to transceiver 304 and through the microelectrode interface to nerve 352 to provide sensory feedback (see col. 15, lines 4-10). Although not explicitly stated, such sensory feedback is necessarily accomplished by utilizing the stimulation mode of the microelectrode interface (in the alternative, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize the stimulation mode of the implanted microelectrode interface to stimulate the sensory nerve in order to provide the person with tactile, position, and force sensation and enhance the function of the prosthetic limb). Examiner considers the electrical signals to approximate a pattern of sensations that would be received from a normal, innervated limb before it was amputated because such signals are applied to the nerve so that the person can realize tactile, position, and force sensations as would be received from a normal limb before it was amputated.

Kovacs fails to disclose that the selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors. As previously stated, Kovacs discloses that prosthetic limb 302 may contain sensors for tactile, position, and force sensing which are transmitted by transceiver 306 to transceiver 304 and through the microelectrode interface to nerve 352 so that the person can realize tactile, position, and force sensations (see col. 15, lines 4-10). It would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors (i.e., patient feedback that stimulation of particular electrodes results in the desired tactile, position, and/or force sensations) in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

Kovacs discloses that a microprocessor (control processor) generates control signals to a stimulus latch 284 to control each pair of microelectrodes for stimulation purposes (see Fig. 9 and associated text). However, Kovacs fails to explicitly disclose the stimulation parameters used for stimulating purposes - in particular, Kovacs fails to disclose that the electrical stimulation signals include impulses having a duration in the range of about 10 to 1000 microseconds and a current amplitude 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber. Anani et al. describes experimentation with nerve stimulation of an

amputation stump, and describes that the stimulus was delivered from a current stimulator providing negative pulses of 0.1 ms width (see first full paragraph on page 132). The intensity range used was between 0.4 mA and 3.0 mA (see first full paragraph on page 132), which is necessarily at a current amplitude 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber because Anani teaches that the subjects felt the stimulation (and thus was necessarily above the current threshold) but that no discomfort or pain was elicited (see Results section on page 132). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Kovacs to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claim 61, Kovacs also fails to disclose that the selection of the electrical stimulation signals is based on feedback from the patient. It is well known to utilize patient feedback for setting effective electrical stimulation parameters such as amplitude and frequency. It would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of the electrical stimulation signals is based on feedback from the patient (i.e., patient feedback that particular stimulation amplitudes or frequencies result in the desired tactile, position, and/or force sensations) as is well known in the art in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

With respect to claims 65 and 82, Anani et al. describes that the stimulus was delivered from a current stimulator providing negative, square shaped pulses of 0.1 ms width (see first full paragraph on page 132). As described above, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Kovacs to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claims 66 and 83, Kovacs does not explicitly teach that the electrical stimulation signals include negative/positive going biphasic pulses. Various tissue stimulators are known in the art for providing biphasic pulses (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Kovacs to utilize such tissue stimulators for applying biphasic pulses since bipolar stimulating pulses significantly reduce the voltage pulse decay time, and thus the level on the electrode leads returns to its quiescent state immediately after each stimulating pulse terminates (see col. 20, lines 33-53 of Schulman).

With respect to claims 68-69, adjustment of stimulation parameters is known in the art (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). For example, it is known that individual thresholds differ from one patient to another, and thus adjustment of the current intensity may be necessary to avoid causing pain or discomfort to the patient. In addition, it is known that patient's may adapt to

stimulation parameters, and thus require an adjustment in order to elicit the desired sensations.

6. Claims 62, 70, 73-74, 76-77, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,314,495 ("Kovacs") in view of "Discrimination of Phantom Hand Sensations Elicited by Afferent Electrical Nerve Stimulation in Below-Elbow Amputees" (Anani et al.), as applied above, and further in view of U.S. Patent No. 4,232,679 ("Schulman").

As described above, Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. Kovacs fails to disclose that electrical stimulation signals are produced in the absence of sensory signals in order to alleviate phantom limb pain. Schulman teaches that it is known in the art to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40). It would have been obvious to one having ordinary skill in the art to modify the microelectronic interface of Kovacs to stimulate an amputee's severed nerve to alleviate phantom limb pain as taught by Schulman because phantom limb pain may occur when the prosthetic limb is not in use (i.e., when the sensors are not controlling the nerve stimulation).

Kovacs also fails to disclose that the selection of the electrical stimulation signals is based on feedback from the patient. It is well known to utilize patient feedback for setting effective electrical stimulation parameters such as amplitude and frequency. It

would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of the electrical stimulation signals is based on feedback from the patient (i.e., patient feedback that particular stimulation amplitudes or frequencies result in the desired tactile, position, and/or force sensations) as is well known in the art in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

With respect to claims 73 and 84, Anani et al. describes that the stimulus was delivered from a current stimulator providing negative, square shaped pulses of 0.1 ms width (see first full paragraph on page 132). As described above, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Kovacs to utilize the stimulation parameters of Anani et al. since Anani teaches that such parameters allow maximum discrimination capacity (see first full paragraph on page 132) without causing pain or discomfort to the patient.

With respect to claims 74 and 85, Kovacs does not explicitly teach that the electrical stimulation signals include negative/positive going biphasic pulses. Various tissue stimulators are known in the art for providing biphasic pulses (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sensory system of Kovacs to utilize such tissue stimulators for applying biphasic pulses since bipolar stimulating pulses significantly reduce the voltage pulse decay time, and thus the level on the electrode leads returns to its quiescent state

immediately after each stimulating pulse terminates (see col. 20, lines 33-53 of Schulman).

With respect to claims 76-77, adjustment of stimulation parameters is known in the art (see, for example, U.S. Patent No. 4,232,679 to Schulman at col. 1, line 10 - col. 2, line 31). For example, it is known that individual thresholds differ from one patient to another, and thus adjustment of the current intensity may be necessary to avoid causing pain or discomfort to the patient. In addition, it is known that patient's may adapt to stimulation parameters, and thus require an adjustment in order to elicit the desired sensations.

Response to Arguments

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

8. In addition, Examiner notes that Applicant's arguments filed 9/18/06 are not persuasive. In particular, one of the amendments to the independent claims include that the electrical stimulation signals have "a current amplitude 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber." Applicant argues that such a parameter (that is, intensity) as well as the adjustment range are believed to involve inventive ingenuity over Riso since these data are not readily available from Riso (see page 14 of Response filed 9/18/06). However, the electrical stimulation signals applied in Riso must necessarily be above the patient's current threshold in order to the subjects to feel the stimulation. In

addition, it is certainly well known in the art to limit the applied intensity of the electrical stimulation such that the subject does not experience pain or discomfort. Thus, Examiner believes that the limitation that the electrical stimulation signals have "a current amplitude 1-10 times a current threshold required to recruit a large diameter sensory nerve fiber without recruiting a pain nerve fiber" does not patentably define the claimed invention over Riso.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
NRK
9/26/06

George Manuel
Primary Examiner